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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,842	06/15/2001	Ginette Serrero	A7542.0000/P001-D	7029

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WASHINGTON, DC 20037-1526

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/25/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/880,842

Examin r

MISOOK YU, Ph.D.

Applicant(s)

SERRERO, GINETTE

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) 13-19, 40-44 and 66-85 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 65 is/are allowed.
- 6) ☒ Claim(s) 1-12, 20-39 and 45-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims 13-19, 40-44, and 66-85 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 13-19, 40-44, and 66-85 **remain withdrawn** for the reasons set forth in the previous Office Action (Paper No. 12) from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-85 are pending and claims 1-12, 20-39, and 45-65 are examined on merits.

Claim Rejections - 35 USC § 112

The rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment and/or on consideration, the many issues raised here are 35 U.S.C. 112, first paragraph enablement issues, but metes and bounds of one's property.

Claims 1-12, 20-39, and 45-64 are rejected for reason of record under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for more than 5 % GM88 positive staining for breast cancer diagnosis, does not reasonably provide enablement for (1) ratio or amount of GP88 positive cells and (2) any other cancer. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues that in vivo data are not necessary in order to satisfy the enablement requirement under 35 U.S.C. 112, first paragraph and the Office agrees.

The data shown in the specification is enabled for only breast cancer diagnosis with greater than 5 % or more ratio of SEQ ID NO:16 encoded protein expression but the claims are drawn to cancer diagnosis in general with any amount other than zero. As discussed in the previous Office action, the art teaches SEQ ID NO:16 encoded protein is expressed in normal tissues. Based on the disclosure of the instant specification or what is known about the protein expression in the art, one in skilled would not conclude or correlate detection of any amount of SEQ ID NO:16 encoded protein to any cancer.

Applicant further argues that all of the detection methods are routine and the Office agrees. The undue experimentation is required for the conclusion step, for example, if an artisan detects 0.5 % ratio SEQ ID NO:16 encoded protein expression in a lung tissue from a patient with art-known method for example, immunochemistry technique, does that mean the patient who provided the lung tissue sample has lung cancer or any other cancer or resistant to cancer therapy?

The Office maintains that correlating any amount of SEQ ID NO:16 encoded protein to any cancer diagnosis or any cancer therapy monitoring other than breast cancer would require undue experimentation. Limiting the scope of the claims to breast cancer diagnosis with more than 5 % or more ration would obviate this rejection.

Claim Rejections - 35 USC § 103

The rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over Shoyab et al (WO 91/15510) is **withdrawn** because applicant's argument is persuasive.

Claim Rejections - 35 USC § 101

Double Patenting

Claims 1-12, 20-26 remain provisionally rejected for reason of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20, 28-56 of copending Application No. 09/456,886.

Allowable Subject Matter

Claim 65 is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-

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308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
September 21, 2003

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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